

and \$670,000 is to be spent by other agencies.

b. Short-Term Benefits

From an estimated base of 6,800 deaths in the population screened which would occur without this program component,^{17/} a 1% reduction in immediate mortality is anticipated due to the successful treatment of acute pyelonephritis (if it is detected at an early stage before severe tissue damage has occurred).^{18/} Therefore, a reduction in mortality of 70 deaths per year is estimated.

In addition, there is a reduction in the prevalence of significant bacteriuria in 3,231,260 patients (50% of 6,462,520). This 50% reduction is based on the supposition that the majority of cases detected will be of simple bacteriuria, in the absence of tissue infection, which responds well to treatment. It is understood that the first course of therapy for patients with bacteriuria in acute infections would be highly successful, but it is not anticipated that a permanent cure will be achieved in individuals with chronic urinary tract infections.

With therapy, the number of morbid days could be reduced by 65% from the base of 24,557,580 to 15,962,427.^{19/}

c. Long-Term Benefits

A significant benefit from this early detection program will be an ultimate reduction in mortality due to end-stage renal disease resulting from earlier urinary tract infections.^{19A/} After a diagnosis of infection is made, further study of the patient would lead to the detection of factors predisposing to or associated with that infection. It should be pointed out that new methods of anti-infectious therapy could possibly increase the cure rate for the population-at-risk to 75%.^{20/}

(1) Annual Long-Term Benefits

At present, it is estimated that 20% (1,750) of an estimated total cases (8,500) of end-stage kidney disease per year can be averted by current medical therapy. ^{21/}

(2) Cumulative Long-Term Benefits

It is estimated that in time 5% (323,126) of the 6,462,520 individuals having significant bacteriuria may have developed a significant urinary tract infection. Of this 5%, approximately 40% (129,250) may eventually die in renal failure. Implementation of the above program would be expected to reduce this mortality by 20% (25,850) based on current methods of therapy. ^{22/}

3. Research

Because of problems peculiar to urinary tract infection, [i.e., the poor response to therapy (20% cure rate) and the difficulty in isolating bacteria from end-stage kidneys resulting from infection], a great deal of research, both laboratory and clinical, must be undertaken before a more effective program can be administered in the prevention of urinary tract infections.

a. Laboratory Research

Laboratory research should be concentrated in these areas:

- 1) A relationship of viral agents to renal disease;
- 2) The identification and treatment of host-factors which predispose the host to urinary tract infections;
- 3) The role of immunologic phenomena in bacterial and/or viral infections of the kidney;
- 4) The role of vascular and metabolic diseases in urinary tract infections;

- 5) The role of various chemical agents (e.g., phenacetin) in renal tissue infection;
- 6) The nature of the exudative response to renal infection;
- 7) The nature of connective tissue proliferation in renal tissue;
- 8) A classification of the organisms causing renal infections and the identification of toxins, enzymes, etc., produced by these organisms; and
- 9) The pharmacology of specific antibiotics including drug inhibitors affecting the viability of microorganisms in renal tissue.

No sound estimate can be made for the cost of each of these basic research programs, but approximately \$1,500,000 should be made available in the form of research grants from HEW.^{23/}

b. Clinical Research

Clinical research must include studies to evaluate therapeutic programs and long-term follow-up of patients with kidney infections, and attempts to identify crucial points in the natural history of the disease at which therapy is most effective. Other studies would be attempted with susceptible patients (pregnant females, persons with obstructive uropathy, diabetics, etc.) to discover pertinent facts in the pathogenesis of renal infection. It is estimated that each large scale clinical study will cost approximately \$500,000 per year.^{24/} This amount is based on existing cooperative studies and does not include the cost of hospitalization or laboratory tests which must be borne by other sources. Four cooperative studies will be developed, each costing \$500,000: one study will address

itself to a study of the natural history of renal infection; two, to therapeutic trials; and a fourth to the pathogenesis of the disease in susceptible sub-groups of patients.

An additional \$500,000 will be used for detailed studies on a small group of patients with renal infection. This study would encompass the definition of changes in renal function, the effects of specific antibacterial agents on the infection, the trial of new treatments such as chronic water loading, etc.

Total clinical research expenditures will amount to \$2,500,000 supported by HEW.

Total costs for research will be \$5,330,000 of which HEW would contribute \$4,000,000; \$1,330,000 would come from other sources.

4. Training

Training includes the financial support of research fellows engaged in clinical laboratory studies, and the cost of relevant facilities. Support and laboratory facilities for approximately 12 fellows for one year would cost HEW approximately \$400,000 plus \$130,000 from other sources, yielding a total of \$530,000.^{25/}

5. Facilities

This program utilizes only existing facilities; however, laboratory and hospital space is limited at present and in order to develop an efficient program as outlined, expanded facilities would undoubtedly be required for research and for the screening of patients for urinary tract infection. Consequently, it is anticipated that about \$1,000,000 would be expended by HEW and an additional \$330,000 by other sources, yielding a total of \$1,330,000.

A benefit-cost summary associated with this program is presented in Table I.

Table I

INFECTIOUS DISEASES OF THE URINARY TRACT, HYPOTHETICAL PROGRAM
AT CURRENT HEW EXPENDITURE LEVEL, BASED ON THE CURRENT STATE OF THE ART

Program	Expenditures		Short-Term Benefits			Long-Term Benefits	
			Reduction Per Year In			Reduction In End-Stage Uremia	
	HEW (\$1,000)	Total (\$1,000)	Mortality	Prevalence	Morbid Days	Per Year	Cumulative
I.A. Screening, diagnosis and treatment of individuals in short and long-term hospitals and nursing homes as well as non-hospitalized pregnant females and diabetics.							
1. Screening	1,803	9,017					
2. Confirming test		84,457					
3. Treatment		54,931					
Sub-Total	1,803	148,405					
B. Supportive education and administration	2,000	2,670					
Sub-Total	3,803	151,075					
II. Research	4,000	5,330					
III. Training	400	530					
IV. Facilities	1,000	1,330					
TOTAL	9,203	158,265	70	3,231,260	15,962,420	1,750	25,850

C. Infectious Diseases of the Urinary Tract, Hypothetical Program at Intermediate HEW Expenditure Level, Based on Current State of the Art

1. Introduction

This program has four components:

- 1) Screening, diagnosis, treatment, and supportive education and administration;
- 2) Research;
- 3) Training; and
- 4) Facilities.

As illustrated in Figure 2, the total cost for this program is estimated to be \$174,252,000, of which HEW funds would account for \$20,179,000. A discussion of the various program components follows.

2. Screening, Diagnosis, Treatment, and Supportive Education and Administration

This program is concerned with the screening, diagnosis and treatment of infections of the urinary tract similar to those described in Section B.2. above. It has, however, been expanded to include all females 6 to 9 years of age who can realistically be reached in a screening program. It is felt that this group can best be reached through screening tests applied in elementary schools.

a. Relevant Population and Program Component Costs

Because of the difficulties anticipated in attempting to reach the entire female population 6 to 9 years of age, it is assumed that a successful program covering a two-year span will be able to reach about 62% of these individuals.^{26/} Of 8,134,000^{27/} females in this age group, 5,040,000 will be reached every two years, and 50% (2,520,000) of these individuals will be screened each year.

Costs (\$1,000,000)

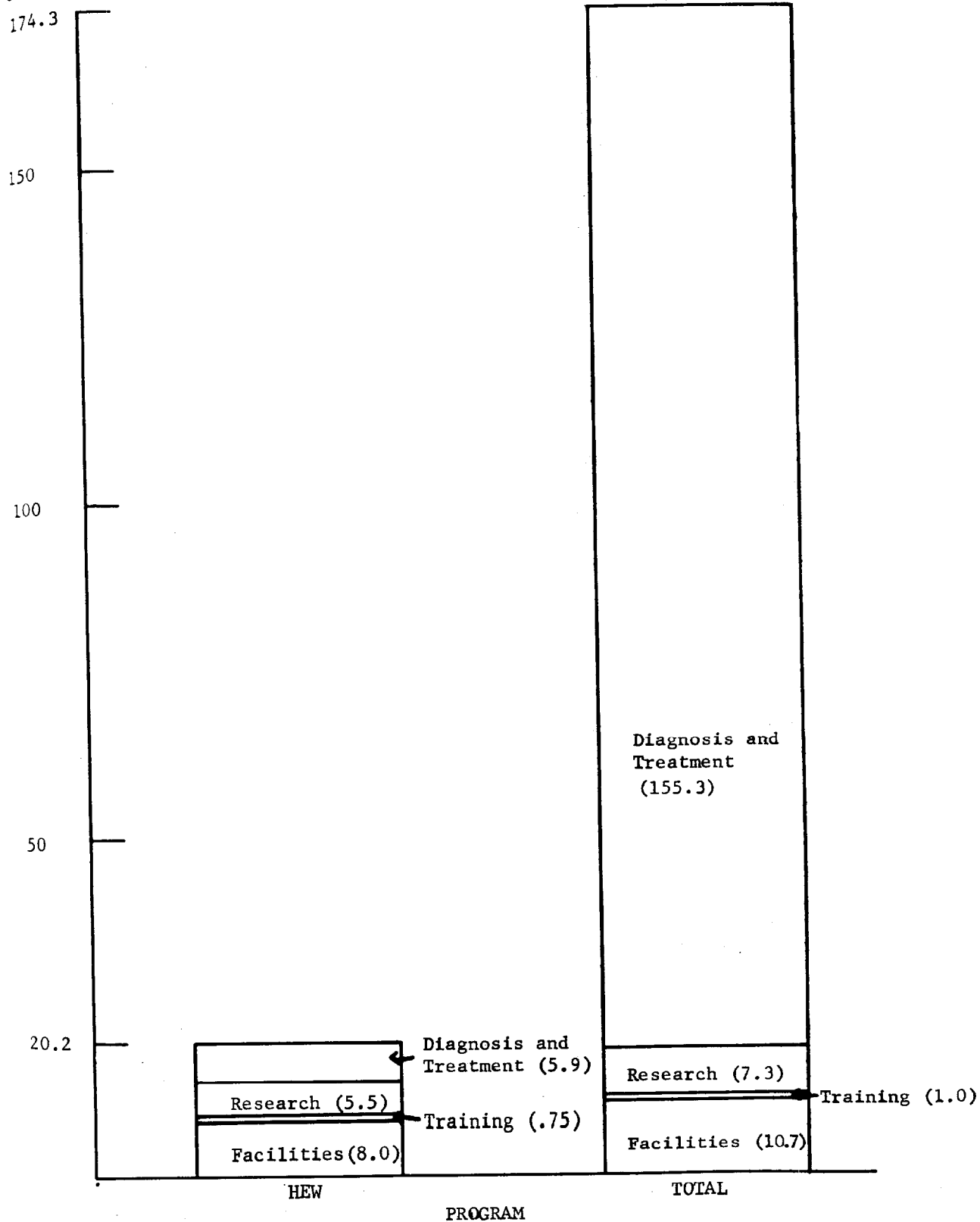


Fig. 2. Infectious Diseases of the Urinary Tract, Hypothetical Program Costs at Intermediate HEW Expenditure Level, Based on the Current State of the Art.

Cost of screening per individual in this additional population is estimated at \$0.25 (as part of a general screening program). If 2,520,000 are screened annually, the total cost will be \$630,000 (\$126,000 from HEW) yearly.

Total cost for screening all the population-at-risk, reached by a general screening program, will be \$9,647,000 (\$1,929,000 from HEW).

It is believed that 1% of these young females (25,200) will have significant bacteriuria.^{29/} It is still assumed that only 85% (21,420) of these individuals can be screened, and that the test has associated with it a 5% false positive value so that 22,491 will have positive results. Confirmatory tests will be necessary both before and after therapy; therefore, at \$7.50 per test, the total cost for confirmatory tests will be \$330,000. For the entire surveyed population, the cost for these confirmatory tests will amount to \$84,787,000, none of which will come from HEW.

The treatment costs for each of the females 6 to 9 years of age is estimated at \$10.00 for drugs and \$15.00 for physicians' services, or a total cost for all of these individuals of \$557,000. Total treatment costs for all groups surveyed having renal infections are \$55,488,000.

The costs outlined above are minimal and are based on conservative estimates. They do not include, for example, intravenous pyelograms and other diagnostic studies necessary for complete diagnosis.

Also note that the overlap in the female population 6 to 9 years of age and the other high-risk groups (that is, the individuals in short and long-term hospitals, nursing homes and the non-

hospitalized pregnant females and diabetics) has not been taken into account and some double-counting may be present.

The supportive education and administration portions of this program component are estimated at a level of \$4,000,000 from HEW and \$1,330,000 from other sources.^{30/} The educational program involves the extensive education of medical personnel throughout the country in the proper uses of catheters and antibiotics, the importance of follow-up studies on individuals with urinary tract infections, the natural history of pyelonephritis, the proper use of diagnostic techniques, etc. The focal centers of the educational program will be community hospitals from which information will be disseminated among appropriate personnel.

Total costs for this program component are estimated at \$155,252,000 (\$5,929,000 from HEW).

b. Short-Term Benefits

In addition to the short-term benefits described in Section B.2. above, the following benefits are expected to result from the screening of these young females:

- 1) Due to the current low mortality rate from urinary infections in females 6 to 9 years of age, no estimate on the reduction of immediate mortality is made;
- 2) A 50% reduction in the prevalence rate from a base of 25,200 to 12,600;^{31/} and
- 3) A 65% reduction of 311,220 in morbid days from a base of 478,000.^{32/}

Total short-term benefits for all groups surveyed are 70 prevented deaths, a reduction in prevalence by 3,243,860, and a

reduction in morbid days by 16,273,640.

c. Long-Term Benefits

(1) Annual Long-Term Benefits

Early diagnosis and treatment of urinary tract infections in this group of females 6 to 9 years of age will decrease the number of cases of renal failure by 20 per year. (A 33% reduction from a base line of 60 which would eventually have acquired end-stage uremia without this program).^{33/}

There will be a reduction by 1,770 cases of end-stage uremia in all relevant groups from a base line of 8,560.^{34/}

(2) Cumulative Long-Term Benefits

Approximately 5% (2,520) of the 50,400^{35/} females with bacteriuria could eventually develop significant urinary tract infections. Approximately 40% (1,010)^{36/} of these individuals would have developed end-stage uremia. Since the females in this age group can be reached at a very early stage of the disease, a reduction in end-stage uremia by 33% (340)^{37/} is anticipated.

About 26,190 cases of eventual renal failure in all groups surveyed will be avoided.

3. Research

Again, clinical and laboratory research are the two major areas of effort. Given increased resources, it is realistic to project that two additional clinical research programs at \$500,000 each could be added to the four existing ones at a total cost of \$3,000,000.

Laboratory research project expenditures could feasibly be increased

to \$2,000,000 (i.e., an increase of \$500,000). Again, a \$500,000 project designed to study susceptible sub-groups of patients is also anticipated. The total HEW support for research is \$5,500,000, and it is anticipated that about \$1,830,000 will be generated from other sources.

4. Training

Training expenditures are estimated to be \$750,000 from HEW with an additional \$250,000 from other sources.

5. Facilities

In the intermediate health program, it is estimated that HEW will provide \$8,000,000 in addition to an expected \$2,670,000 from other sources.

A benefit-cost summary associated with this program is presented in Table II.

Table II

INFECTIOUS DISEASES OF THE URINARY TRACT, HYPOTHETICAL PROGRAM
AT INTERMEDIATE HEW EXPENDITURE LEVEL, BASED ON THE CURRENT STATE OF THE ART

Program	Expenditures		Short-Term Benefits			Long-Term Benefits	
			Reduction Per Year In			Reduction In End-Stage Uremia	
	HEW (\$1,000)	Total (\$1,000)	Mortality	Prevalence	Morbid Days	Per Year	Cumulative
I.A. Screening, diagnosis and treatment of individuals in short and long-term hospitals and nursing homes as well as non-hospitalized pregnant females, diabetics and females 6 to 9 years of age.							
1. Screening	1,929	9,647					
2. Confirming		84,787					
3. Treatment		55,488					
Sub-Total	1,929	149,922					
B. Supportive education and administration	4,000	5,330					
Sub-Total	5,929	155,252					
II. Research	5,500	7,330					
III. Training	750	1,000					
IV. Facilities	8,000	10,670					
TOTAL	20,179	174,252	70	3,243,860	16,273,640	1,770	26,190

D. Infectious Diseases of the Urinary Tract, Hypothetical Program at Accelerated HEW Expenditure Level, Based on Current State of the Art

1. Introduction

This program has four components:

- 1) Screening, diagnosis, treatment, and supportive education and administration;
- 2) Research;
- 3) Training; and
- 4) Facilities.

As illustrated in Figure 3, the total cost for this program is estimated at \$189,013,000, of which HEW will contribute \$27,394,000.

A detailed discussion of the various program components follows.

2. Screening, Diagnosis, Treatment, and Supportive Education and Administration

In addition to the high risk groups surveyed in Section B.2., this program component has been expanded to include all females 21 years of age and under. It is again postulated that the expected rewards from controlling infectious diseases of the urinary tract in these females would be sizeable enough to merit its consideration. It is desirable to reach the majority of females in this age group through schools, colleges, and various youth programs such as Operation Headstart.

a. Relevant Population and Program Component Costs

A successful program will probably reach approximately 60% of the relevant female population. This program will again cover a two-year span so that one-half of this population will be screened every year. Therefore, of the 41,065,000 females 21 years of age and under in the U. S., ^{38/} 12,319,500 will be screened each year [i.e., 24,639,000 (approximately 60%) of the total will be reached in

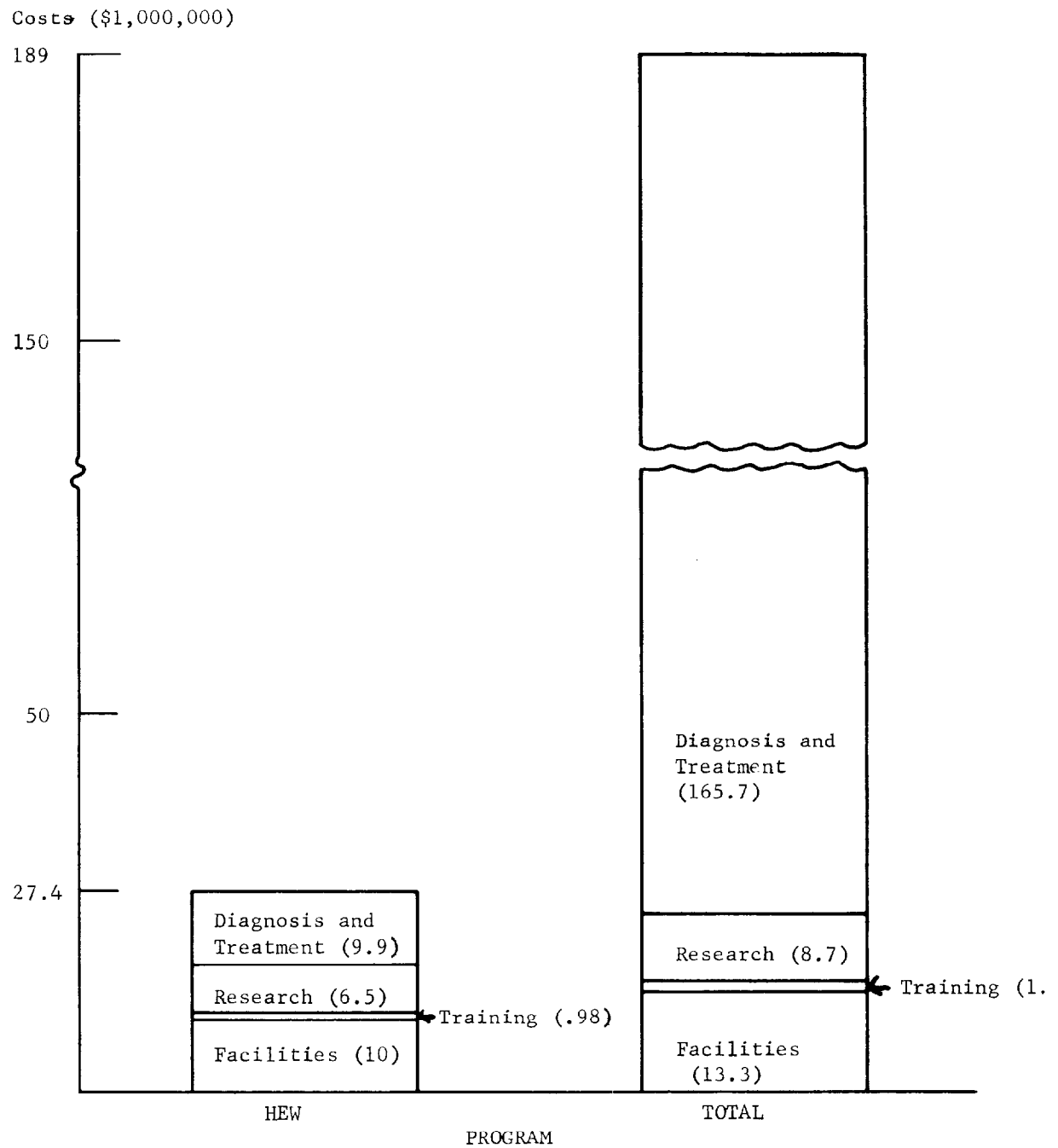


Fig. 3. Infectious Diseases of the Urinary Tract, Hypothetical Program Costs at Accelerated HEW Expenditure Level, Based on the Current State of the Art.

two years, and 50% of these, or 12,319,500, will be reached every year]. It is estimated that about 1% of the females 21 years of age and under, 246,390, will have significant bacteriuria; therefore, 123,195 will be detected each year. It is to be emphasized that this figure is quite conservative since it is known that females 12 to 16 years of age have a high incidence of bacteriuria,^{39/} and while no information was available regarding the incidence of bacteriuria in college-age females, it may be even higher than that of other school-age females.

Screening costs in this female population are estimated at \$0.25 per person (as part of a general screening program). If 12,319,500 are screened annually, the total cost will be \$3,080,000 (\$616,000 from HEW).

Total screening costs for all the surveyed populations (including those described in Section B.2.) will be \$12,097,000 (\$2,419,000 from HEW).

The number of confirmatory tests required for females 21 years of age and under will be 109,952 pre-therapy and 104,716 post-therapy tests,^{40/} and the cost for these tests will be \$1,610,000 assuming a rate of \$7.50 per test.

For all the surveyed populations (including those described in Section B.2.) the total cost for confirmatory tests will be \$86,067,000, none of which is assumed to come from HEW.

The treatment costs for each female 21 years of age and under with a confirmed diagnosis of renal infection is estimated at \$10.00 for drugs and \$15.00 for physicians' services. This means that the

total cost for these affected females is \$2,618,000, all of which comes from sources other than HEW.

Total treatment costs for all population groups surveyed having renal infections are \$57,549,000.

The costs outlined are minimal and do not include such items as intravenous pyelograms and other diagnostic studies which are necessary for a complete diagnosis.

Again, the overlap of the female population, 21 years of age and under, and the other high-risk groups has not been taken into account and some repetitious counting may be present.

The supportive education and administrative portion of this program component is estimated to be \$7,500,000 from HEW and \$2,500,000 from other sources. It is anticipated that the educational program will be intensified and similar to the one described in Section C.2.a.

The total cost for this program component is estimated at \$165,713,000 (\$9,919,000 from HEW).

b. Short-Term Benefits

In addition to the short-term benefits described in Section B.2.b. above, the following results can be anticipated from a screening program in females 21 years of age and under:

- 1) No estimates were made on the reduction of immediate mortality due to the very low mortality rates from urinary tract infection in this population;
- 2) A 50% reduction (61,600) in prevalence rate from a base of 123,195; $\frac{41}{100}$ and
- 3) A 65% reduction of 1,521,460 in morbid days from a base

of 2,340,710.^{42/}

Total short-term benefits in all groups surveyed with renal infections are 70 prevented deaths, a reduction in prevalence of cases by 3,292,860, and a reduction in the number of morbid days by 17,483,880.

c. Long-Term Benefits

(1) Annual Long-Term Benefits

As a result of the early diagnosis and administration of treatment of urinary tract infections, a 33% reduction in the number of annual cases of renal failure is anticipated. This would amount to a decrease of 120 cases from a base line of 360 cases per year.

There will be a reduction by 1,870 cases of renal failure in all relevant groups from a base line value of 8,860 cases which would have occurred without this program.^{43/}

(2) Cumulative Long-Term Benefits

Of the 246,390 females with significant bacteriuria who can be reached by this program, approximately 5% (12,320) would eventually develop significant urinary tract infection.^{44/} Of this group approximately 40%, 4,930, would eventually die in renal failure.^{45/} Implementation of the above program would be expected to reduce this mortality figure by 33%, or 1,630.^{46/}

A total of 27,480 cases of renal failure in all groups surveyed would be avoided.

3. Research

Given the increased resources of this accelerated program, the number of clinical research projects could be doubled from the current level of 4

to 8 projects at \$500,000 each for a total of \$4,000,000.

Laboratory research expenditures could feasibly be set at \$2,000,000, with an additional \$500,000 available for projects designed to study susceptible sub-groups of patients.

Thus, the total HEW support for research would be \$6,500,000. It is anticipated that an additional \$2,170,000 would be contributed by other sources.

4. Training

Training costs are estimated to be 15% of the research expenditures i.e., \$1,300,500, of which \$975,000 comes from HEW, and an additional \$325,500 from other sources.

5. Facilities

With an accelerated health program, it is estimated that HEW will expend about \$10,000,000 for facilities in addition to \$3,330,000 contributed by other sources.

A benefit-cost summary associated with this program is presented in Table III.

Table III

INFECTIOUS DISEASES OF THE URINARY TRACT, HYPOTHETICAL PROGRAM
AT ACCELERATED HEW EXPENDITURE LEVEL, BASED ON THE CURRENT STATE OF THE ART

Program	Expenditures		Short-Term Benefits			Long-Term Benefits	
			Reduction Per Year In			Reduction In End-Stage Uremia	
	HEW (\$1,000)	Total (\$1,000)	Mortality	Prevalence	Morbid Days	Per Year	Cumulative
I.A. Screening, diagnosis and treatment of individuals in short and long-term hospitals and nursing homes as well as non-hospitalized pregnant females, diabetics, and females 21 years of age and under.							
1. Screening	2,419	12,097					
2. Confirming		86,067					
3. Treatment		57,549					
Sub-Total	2,419	155,713					
B. Supportive education and administra- tion	7,500	10,000					
Sub-Total	9,919	165,713					
II. Research	6,500	8,670					
III. Training	975	1,300					
IV. Facilities	10,000	13,330					
TOTAL	27,394	189,013	70	3,292,860	17,483,880	1,870	27,480

E. Infectious Diseases of the Urinary Tract, Hypothetical Program for Fiscal Year 1975, at Accelerated HEW Expenditure Level, Based on Expected State of the Art in 1975

1. Introduction

This program has four components:

- 1) Screening, diagnosis, treatment, and supportive education and administration;
- 2) Research;
- 3) Training; and
- 4) Facilities.

The total estimated cost for this program is \$215,471,000 of which HEW will contribute \$31,228,000 (see Figure 4). Under an advanced state of the art it is assumed that the research efforts undertaken have made possible 1) more effective antimicrobial therapy, and 2) a better understanding of the pathophysiology of urinary tract infection, with new treatment methods for predisposing factors which sometimes lead to bacteriuria. A detailed discussion of the various program components follows.

2. Screening, Diagnosis, Treatment and Supportive Education and Administration

In 1975 the total U. S. population will have increased by 14%^{47/} but there are no anticipated changes in the nature of the relevant population.

a. Relevant Populations and Program Component Costs

It is estimated that of a projected 33,227,580 hospitalized and nursing home residents, 6,645,520 will have significant bacteriuria (a 20% prevalence rate).^{48/} The non-hospitalized pregnant female population is estimated to be 5,126,580;^{49/} assuming a

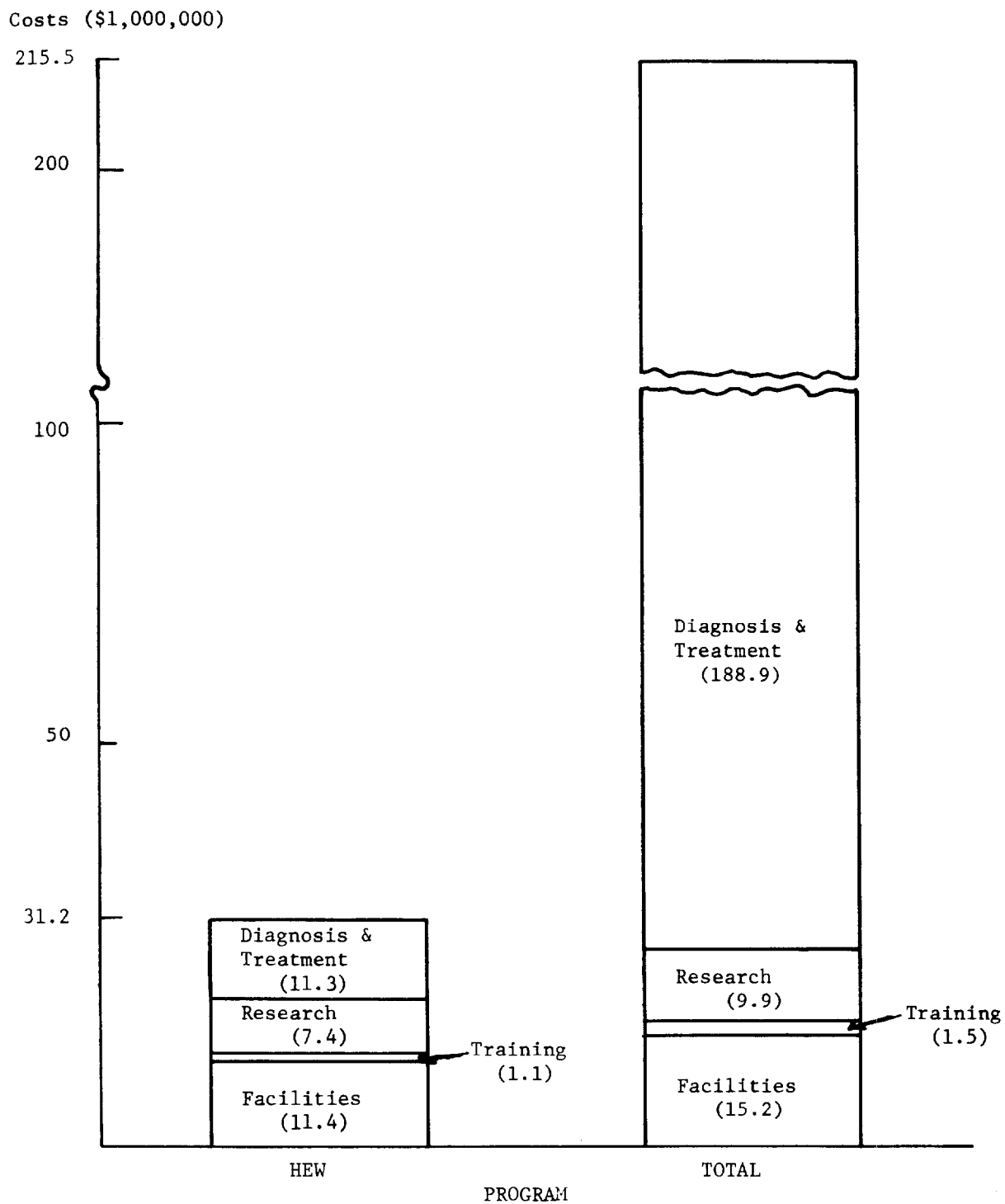


Fig. 4. Infectious Diseases of the Urinary Tract, Hypothetical Program Costs for Fiscal Year 1975, at Accelerated HEW Expenditure Level, Based on Expected Advanced State of the Art in 1975.

prevalence rate of 6% for bacteriuria, 307,590 persons will have positive screening tests. The non-hospitalized diabetic population will be 2,761,080^{50/} and approximately 414,160 will have bacteriuria (assuming a 15% prevalence rate in the diabetic population). While it is possible that significant improvements in the treatment and diagnosis of diabetics will have occurred, this assumption was not made. It is anticipated that 14,044,230 females under 21 years of age will be screened yearly; 140,440 of these women will have significant bacteriuria, assuming a 1% prevalence rate.^{51/} (Note it is still assumed that only 60% of the females 21 years of age and under can be reached, and that the screening program will cover a two-year span.)

Cost of screening will be \$13,790,000 (\$2,758,000 to be borne by HEW). It is still assumed that the cost per test under a general screening program will be \$0.25, and this cost is applied to the 55,159,440^{52/} individuals to be screened each year.

The cost of confirmatory tests remains at \$7.50 per person. Total cost is approximately \$98,150,000, excluding a second repeat test for false-positive patients.

Treatment costs also remain the same, i.e., \$10.00 for drugs for those individuals who are already under a physician's care. It is estimated that there are 6,262,180 of these individuals yielding a cost of \$62,622,000. For those individuals who would not have been under a physician's care (the female population 21 years of age and under), \$15.00 per individual for physicians' services is added. The cost of treatment for this group is \$2,984,000 (119,374 x \$25).^{53/}

Total cost of treatment is thus estimated to be \$65,606,000.

HEW is not responsible for the cost of confirmatory tests or treatment.

Total cost for this initial portion of the program component is \$177,511,000, of which \$2,758,000 is to be borne by HEW.

Support for education and administration is estimated to cost \$8,550,000 for HEW, to include a more extensive educational program to reach the increased population. An additional \$2,850,000 will come from outside sources.

Therefore, the total cost for this program component is \$188,911,000, of which \$11,308,000 comes from HEW.

b. Short-Term Benefits

The estimated short-term benefits are as follows:

- 1) From a base line of 7,750 deaths in the group surveyed which would have occurred in the absence of any program, a reduction of 80 deaths is estimated;^{54/}
- 2) It is estimated that there will be an 85% reduction (5,630,780) in prevalence from 7,507,710 cases [35 of the 85% (1,876,930) can be attributed to advances in the state of the art];^{55/} and
- 3) It is estimated that the number of morbid days will be reduced by 85% (26,064,430) from a base line figure of 30,664,040 (20 of the 85% reduction, i.e., 6,132,810 is attributed to advances in the state of the art).^{56/}

c. Long-Term Benefits

(1) Annual Long-Term Benefits

It is estimated that approximately 7,500 of the group

surveyed per year will have developed end-stage renal failure without the program. Ideally this program would reduce this number by 55%, or 4,125 per year [of which 2,250 (approximately 30 of the 55% reduction) are due to advances in the state of the art].^{57/}

(2) Cumulative Long-Term Benefits

About 5% of the individuals with bacteriuria would have developed significant urinary tract infections in the absence of any program. Approximately 40% of these persons would eventually die from uremia. Within the relevant population, there would be 7,658,160 individuals having bacteriuria.^{58/}

It can then be said that some 382,400 will probably develop significant urinary tract infections and 40%, or 153,000, of these would eventually die from uremia. It is estimated that the number of deaths resulting from end-stage kidney failure can be reduced by 55% or 84,150 (approximately 30 of the 55%, or 45,900, of the reduced number of deaths is due to advances in the state of the art).^{59/}

3. Research

Research expenditures will be increased in amount to \$7,410,000 which will come from HEW, and an additional \$2,470,000 to come from other sources. It is anticipated that a cure for urinary tract infections may be found through the development of new antibiotics and new treatment methods for predisposing factors which sometimes lead to bacteriuria.

4. Training

Money expended for training purposes will total \$1,480,000, about

15% of that spent for research. Of this amount, \$1,110,000 will come from HEW and an additional \$370,000 from other sources.

5. Facilities

In an accelerated Health Program it is estimated that HEW will contribute \$11,400,000 for facilities, Additional sources will contribute \$3,800,000.

A benefit-cost summary associated with this program is presented in Table IV.

F. Benefits Dependent on New Research Developments ^{60/}

An annual reduction by 1,876,930 in the prevalence rate of renal infection and by 6,132,810 in the number of morbid days will be the short-term effects of new research developments. These statistics take into account a postulated 14% increase in the population of the U. S. from 1966 to 1975. Benefits based on 1966 population figures reveal a reduction in prevalence by 1,646,430 and in the number of morbid days by 5,379,660.

In assessing the annual long-term benefits dependent on new developments, it is estimated that there will be a reduction of 2,250 cases of end-stage kidney disease per year, (1,970 cases based on 1966 U. S. population). Cumulative long-term benefits reveal that 50,650 (44,430 based on 1966 U. S. population) cases of renal failure will be avoided with the advent of new developments and techniques concerned with chronic kidney infections.

Table IV

INFECTIOUS DISEASES OF THE URINARY TRACT, HYPOTHETICAL PROGRAM FOR FISCAL YEAR 1975
 AT ACCELERATED HEW EXPENDITURE LEVEL, BASED ON EXPECTED ADVANCED STATE OF THE ART IN 1975

Program	Expenditures		Short-Term Benefits			Long-Term Benefits	
			Reduction Per Year In			Reduction In End-Stage Uremia	
	(\$1,000)	(\$1,000)	Mortality	Prevalence	Morbid Days	Per Year	Cumulative
I.A. Screening, diagnosis and treatment of individuals in short and long-term hospitals and nursing homes as well as non-hospitalized pregnant females, diabetics, and females 21 years of age and under.							
1. Screening	2,758	13,790					
2. Confirming		98,115					
3. Treatment		65,606					
Sub-Total	2,758	177,511					
B. Supportive education and administration	8,550	11,400					
Sub-Total	11,308	188,911					
II. Research	7,410	9,880					
III. Training	1,110	1,480					
IV. Facilities	11,400	15,200					
TOTAL	31,228	215,471	80	5,630,780	26,064,430	4,125	84,150

III. HYPERSENSITIVITY DISEASES OF THE KIDNEY

A. Introduction

This section describes program efforts projected to control renal disease resulting from hypersensitivity phenomena.

In 1966, an estimated 12,719^{61/} deaths resulted from kidney disease associated with hypersensitivity reactions; 106,000 individuals are estimated to have had hypersensitivity diseases of the kidney, requiring 4,074,000 days of restricted activity, 1,834,000 days of bed disability, as well as 777,000 work-loss days.^{62/}

Four programs are considered in this analysis and discussed in detail below (see Chapter 5, Research Methodology).

B. Kidney Diseases Related to Hypersensitivity Phenomena, Hypothetical Program at Current HEW Expenditure Level, Based on the Current State of the Art

1. Introduction

This program has four components:

- 1) Education and administration;
- 2) Research;
- 3) Training; and
- 4) Facilities.

The total cost for this program is estimated to be \$9,975,000 of which HEW's share is \$7,480,000. Figure 5 illustrates costs for the various program components, and they are discussed below.

2. Education and Administration

In order to bring an effective educational program to physicians, it is necessary to supply the approximately 7,000 hospitals in the U. S. with appropriate materials and other educational support. Estimating a cost of \$140 per hospital, approximately \$1,000,000 will be needed for

Costs (\$1,000,000)

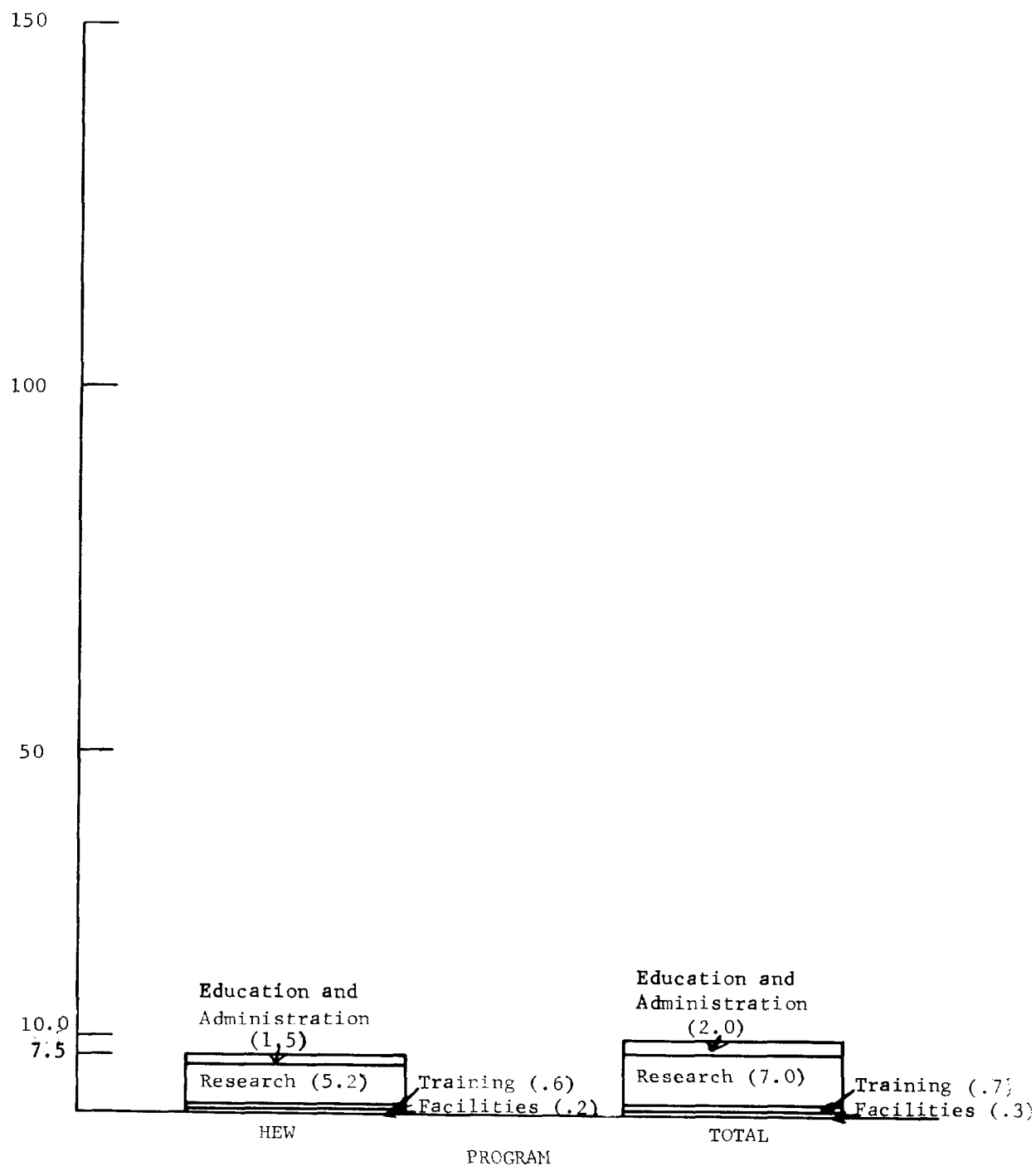


Fig. 5. Kidney Diseases Related to Hypersensitivity Phenomena, Hypothetical Program Costs at Current HEW Expenditure Level, Based on Current State of the Art.

instruction in this area of kidney disease as part of a general educational program. In addition, about \$500,000 will be required for the administration and implementation of this program. The total cost for HEW is then estimated at \$1,500,000. An additional \$500,000 is expected from other sources.

Under the current state of the art postgraduate physician education seems to be the most effective approach for achieving immediate benefits.

a. Short-Term Benefits

It is estimated that this educational program would decrease the immediate annual mortality due to hypersensitivity diseases by approximately 5% (610) from a base line of 12,719⁶³/deaths per year. This figure is based on the assumption that improved understanding of diseases such as acute glomerulonephritis, and improved knowledge of fluid, electrolyte, and steroid therapy will have some impact on the immediate mortality from diseases associated with hypersensitivity phenomena.

b. Long-Term Benefits

Under the present state of the art, no long-term benefits are anticipated.

3. Research

This most important program component is separated into clinical and laboratory research efforts.

a. Clinical Research

Following are some areas of disease which need clarification and study to determine their significance in hypersensitive renal disease:

- 1) Minimal persistent proteinuria;
- 2) Orthostatic proteinuria;
- 3) Childhood nephrotic syndrome;
- 4) Adult nephrotic syndrome;
- 5) Acute glomerulonephritis;
- 6) Systemic lupus erythematosus;
- 7) Miscellaneous collagen diseases; and
- 8) Any other related hypersensitivity diseases having renal involvement.

The estimated cost for each study area is \$500,000, yielding a total cost of \$4,000,000 (\$3,000,000 from HEW).

Following are some comments on the present status in each of the above study areas:

- 1) Several universities have been approached on the possibility of conducting cooperative studies on the diseases listed above and have expressed interest in them. No further progress has been made due to a shortage of funds.
- 2) The Air Force is currently studying orthostatic proteinuria at Lackland Air Force Base, Texas.
- 3) There is an international cooperative study being conducted on the childhood nephrotic syndrome under the direction of Dr. Henry Barnett of the Albert Einstein Medical Center in New York City.
- 4) There is no coordinated activity on the adult nephrotic syndrome at the present time in the United States. However, in Great Britain, there is a study sponsored by the British

Medical Research Council on the controlled treatment of adult nephrotics with steroids.

- 5) There is a loose cooperative study on acute glomerulonephritis under way in New York City. There is also a study being supported on the island of Trinidad which is designed to follow patients with acute glomerulonephritis. The resurgence of the Red Lake epidemic of acute glomerulonephritis is also under study by Dr. Wanamaker's group at the University of Minnesota.
- 6) There is a loose cooperative study by several university centers emphasizing the pathology in nephritis resulting from systemic lupus erythematosus.
- 7) Other disease processes that might be grouped under the heading of hypersensitivity diseases are sub-acute glomerulonephritis, chronic glomerulonephritis, serum sickness nephritis, and nephrotoxic nephritis in animals.

b. Laboratory Research

There are at present approximately 30 immunology research units in existence. It is estimated that approximately 15 of these units are currently engaged in work which is applicable to hypersensitivity diseases of the kidney. The total contribution of funds for relevant studies to these laboratories would be approximately \$1,500,000 (\$100,000 each) per year, of which HEW would contribute \$1,125,000. In addition, it is estimated that an additional \$1,500,000 (\$1,125,000 from HEW) should be made available for grant support of individual

projects in other laboratories. At an average cost of \$25,000 each this amount would support the work of 60 investigators.

It is assumed that the total of \$7,000,000 as described in the above categories will come from both federal and private funds, with the majority coming from HEW.

4. Training

It is anticipated that each of the 15 involved immunology laboratories would provide training for two research fellows per year. The cost for this program would be approximately \$50,000 per laboratory per year,^{64/} or a total of \$750,000 for the whole program (\$560,000 from HEW).

5. Facilities

In order to continue expanding research capabilities and updating the necessary equipment, it is estimated that 15% of the yearly cost of laboratory research operations will be spent. The total cost of equipment updating for 15 laboratories amounts to \$225,000 per year (15% of which, \$170,000, comes from HEW).

6. Summary

The preceding discussion and estimates presume activity on a level considerably above the current status. There is a substantial initial cost in achieving the new elevated level of activity. Principal among these costs is the expense of constructing and providing adequate facilities. This amount should not be confused with the facilities estimate discussed above which is for the improvement of equipment intended to keep research workers supplied with the best equipment for their varied programs.

A benefit-cost summary associated with this program is found in

Table V.

Table V

KIDNEY DISEASES RELATED TO HYPERSENSITIVITY PHENOMENA, HYPOTHETICAL PROGRAM AT CURRENT HEW
EXPENDITURE LEVEL, BASED ON THE CURRENT STATE OF THE ART

Program	Expenditures		Short-Term Benefits			Long-Term Benefits	
			Reduction Per Year In			Reduction In End-Stage Uremia	
	HEW (\$1,000)	Total (\$1,000)	Mortality	Prevalence	Morbid Days	Per Year	Cumulative
I. Education and administration	1,500	2,000					
II. Research	5,250	7,000					
III. Training	560	750					
IV. Facilities	170	225					
TOTAL	7,480	9,975	610	—	—	—	—